

2004

**LEGISLATIVE ASSEMBLY FOR THE AUSTRALIAN
CAPITAL TERRITORY**

Human Cloning (Prohibition) Bill 2004

EXPLANATORY STATEMENT

Circulated by the authority of the Minister for Health

Simon Corbell MLA

Human Cloning (Prohibition) Bill 2004

EXPLANATORY STATEMENT

Overview

The object of this Bill is to adopt in the ACT a uniform Australian approach to the prohibition of human cloning and certain other practices associated with reproductive technology. This Bill:

- (a) makes it an offence (punishable by 15 years imprisonment):
 - (i) to intentionally create a human embryo clone, or
 - (ii) to intentionally place a human embryo clone in the body of a human or animal, and
- (b) creates a number of other offences (punishable by 10 years imprisonment) that prohibit practices associated with reproductive technology.

NOTES ON CLAUSES

PART 1 PRELIMINARY

Clause 1—Name of Act

This is a formal provision that sets out the name (also called the short title) of the proposed Act.

Clause 2—Commencement

Clause 2 provides that the Act will take effect on the day after it is notified on the ACT Legislation Register.

Clause 3—Dictionary

Clause 3 provides that the dictionary at the end of the Act is a part of the Act.

Clause 4—Notes

This clause provides that notes contained in the Act are explanatory and are not a part of the Act.

Clause 5—Offences against Act—application of Criminal Code etc

This clause provides that other legislation will apply in relation to offences against the *Human Cloning Bill 2004*.

Clause 6—Object of Act

This clause states the object of the proposed Act, which is principally to adopt in the ACT a uniform Australian approach to the prohibition of human cloning, and certain other practices associated with reproductive technology.

Clause 7—Meaning of *human embryo*

This clause defines the term human embryo to mean a live embryo that has a human genome or an altered human genome, that has been developing for less than 8 weeks since the appearance of 2 pro-nuclei or the initiation of its development by other means. In determining the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

This definition is intended to include:

- a. *a human embryo created by the fertilisation of a human egg by human sperm.*

The Bill relies upon the appearance of 2 pro-nuclei to establish the existence of a human embryo that has been created by the fertilisation of a human egg by human sperm. The appearance of the pro-nuclei indicates that the nuclei from the sperm and the egg are aligning prior to possible fusion. For the purposes of this legislation, the 8 weeks of development is taken to start with the appearance of 2 pro-nuclei. The legislation does not rely on defining when fertilisation commences or is complete.

- b. *a human embryo that has had its development initiated by any means other than by the fertilisation of a human egg by human sperm.*

It is intended that the definition include the following types of embryos:

- a human egg that has had its nucleus replaced by the nucleus of a somatic cell (ie a cell from the body) by the process referred to as somatic cell nuclear transfer (SCNT); and
- a parthenogenetic human embryo. It is possible that a human egg could be mechanically or chemically stimulated to undergo spontaneous activation and exhibit some of the characteristics of a fertilised human egg. A parthenogenetic human embryo has the capacity to continue its development in a similar manner to a human

embryo created by fertilisation.

It should be noted that the procedures outlined above are provided as examples only as there may be other ways that the development of an embryo may be initiated. For the purposes of the legislation the 8 weeks of development is taken to start with the initiation of development by other means.

Subclause 7(2) clarifies that for the purposes of the definition of “human embryo”, in working out the length of period of development of a human embryo, any period when development of the embryo is suspended (for example, while it is frozen) is not included. For example, if an embryo is placed in storage 2 days after fertilisation and is held in storage for 10 weeks, it is still considered to be a 2 day embryo in terms of its development.

Clause 8—Meaning of *human embryo clone*

Clause 8 defines “human embryo clone”, which is defined to mean a human embryo that is a genetic copy of another living or dead human, but does not include a human embryo created by the fertilisation of a human egg by human sperm.

The reference to a human embryo clone not including a human embryo created by the fertilisation of a human egg by human sperm is to ensure that identical twins (or other identical multiples) that occur through the spontaneous division of an embryo (created by fertilisation) into two (or more) identical embryos are not defined as human embryo clones.

Subclause 8(2) clarifies that in order to establish that a “human embryo clone” is a genetic copy of a living or dead human, it is sufficient to establish that a copy has been made of the genes in the nuclei of the cells of another living or dead human. Further, the copy of the genes does not have to be an identical genetic copy. This means that the human embryo clone does not have to be genetically identical to the original human. This allows for:

- the presence of DNA outside the nucleus (ie mitochondrial DNA) that is not identical to the living or dead human from which the nuclear DNA was taken, as would occur in an embryo created using the somatic cell nuclear transfer technique;
- spontaneous changes to the nuclear DNA that may occur during the development of a human embryo clone; and
- the deliberate alteration of the DNA so that the intention is to produce a clone of another human, but where the nuclear DNA could no longer be considered an identical copy of the original DNA. This point is also addressed within the definition of “human embryo”, which includes one that has an altered human genome. As such, an embryo that is a clone of another human and has had its genome deliberately altered will still

be considered a human embryo and therefore, as its original genome was copied, a human embryo clone.

Subclause 8(3) clarifies that for the purposes of the definition of "human embryo clone", a human embryo created by the technological process known as embryo splitting is taken not to be created by a process of fertilisation of a human egg by human sperm and is therefore considered to be a human embryo clone. Embryo splitting is a technique that may be carried out on an embryo created by in vitro fertilisation, whereby micro-surgical techniques are used to divide an embryo in the early stages of development to produce two or more identical embryos.

PART 2 PROHIBITED PRACTICES

DIVISION 2.1—Human cloning

Clause 9—Offence—creating a human embryo clone

This clause makes it an offence to intentionally create an embryo that is a genetic copy of another living or dead human.

Creating a human embryo clone by any means is an offence. That is, if any current procedures, like somatic cell nuclear transfer, embryo splitting, or any future procedures are used in an attempt to create a human embryo clone, then an offence is committed.

This clause is not intended to capture the circumstance where a human embryo created by assisted reproductive technology, spontaneously divides into two or more identical embryos (commonly known as identical twins, triplets etc). Clause 8 clarifies that identical twins (created by the fertilisation of a human egg by human sperm) are not "human embryo clones".

The maximum penalty that may be applied for creating a human embryo clone is 15 years imprisonment.

Clause 10—Offence—placing human embryo clone in body of human or animal

This clause makes it an offence to intentionally place into the body of a human or an animal a human embryo that is a genetic copy of another living or dead human.

The maximum penalty that may be applied for placing a human embryo clone in the human body or the body of an animal is 15 years imprisonment.

Clause 11—Offence—importing or exporting human embryo clone

This clause makes it an offence to intentionally import a human embryo clone into the ACT or intentionally export a human embryo clone from the ACT. This ensures that all avenues for obtaining a human embryo clone in the ACT are covered, whilst ensuring that a person cannot export a human embryo clone that has been illegally created or obtained.

The maximum penalty that may be applied for importing or exporting a human embryo clone is 15 years imprisonment.

Clause 12—No defence that human embryo clone could not survive

This clause provides that any human embryo clone that is intentionally created, implanted, imported or exported does not have to survive to the point of live birth in order for an offence to be established under clauses 9, 10 or 11.

This would include, but is not necessarily limited to, the following situations:

- where an unsuccessful attempt to create a human embryo clone is made;
- where a human embryo clone is created and then allowed to die;
- where a human embryo clone is created and deliberately destroyed without attempting implantation;
- where a human embryo clone is placed in a woman's reproductive tract, but does not successfully implant in the uterus;
- where a human embryo clone is successfully implanted and begins to develop and then spontaneously terminates;
- where a human embryo clone is successfully implanted and begins to develop and is deliberately terminated; or
- where a human embryo clone is successfully implanted, develops to full term but is still-born.

DIVISION 2.2—Other prohibited practices

Clause 13—creating a human embryo otherwise than by fertilisation etc.

The effect of this clause is that a human embryo intentionally created outside the body of a woman must only be created by the fertilisation of a human egg by human sperm. As such, an embryo must not be created by embryo splitting, by parthenogenesis, by somatic cell nuclear transfer or by any other technique that does not involve fertilisation of a human egg by human sperm. It is also an offence to develop a human embryo created by a means other than the fertilisation of a human egg by human sperm.

The maximum penalty that may be applied for creating a human embryo other than by fertilisation of a human egg by human sperm is 10 years imprisonment.

Clause 14—Offence—creating human embryo for purpose other than achieving pregnancy

The effect of this clause is that a person can only create a human embryo outside the body of a woman if it is intended, at the time of creation, that the embryo could be implanted in an attempt to achieve pregnancy in a particular woman.

It is an offence to create human embryos specifically for other purposes such as for use in research or to derive embryonic stem cells for potential therapeutic use. This clause is not intended to prohibit certain uses of human embryos that are carried out as a part of attempting to achieve pregnancy in a woman in ART clinical practice, such as carrying out diagnostic procedures (such as Pre-Implantation Genetic Diagnosis) or undertaking therapeutic procedures on the embryo.

Further, it is not intended that this clause:

- restrict the number of embryos that may be created for the purposes of achieving pregnancy in a particular woman. The number of embryos created for the reproductive treatment of a particular woman needs to be determined on a case by case basis as a part of routine ART clinical practice; or
- prevent the circumstance whereby a human embryo created by an ART clinic, originally intended for implantation into a woman, may be found not to be suitable for implantation, or may at some point not be required by the woman for whom it was originally created.

The maximum penalty that may be applied for creating a human embryo for a purpose other than achieving pregnancy in a woman is 10 years imprisonment.

Clause 15—Offence—creating etc human embryo containing genetic material from more than 2 people

This clause makes it an offence to intentionally create a human embryo containing genetic material provided by more than 2 people. It is also an offence to develop a human embryo containing genetic material provided by more than 2 people.

One of the effects of this clause is to ban a relatively new ART technique known as cytoplasmic transfer. Cytoplasmic transfer involves the injection of some of the cytoplasm (the part of the cell outside the nucleus) from a

healthy, donor egg into a recipient patient's egg, with the aim of overcoming certain problems that the patient has with regards to achieving pregnancy. It has been reported that this procedure may be particularly valuable to older women to assist them to become pregnant.

Both safety and ethical concerns have been raised regarding cytoplasmic transfer. Firstly, the technique is a very new technique and its safety with respect to babies created using the technique is yet to be established. Additionally, any live born child may have DNA from three separate people, posing ethical concerns. The DNA from the third party (the donor of the healthy egg) would be mitochondrial DNA, which is thought not to have an impact on the physical characteristics of the child. However, the impact (if any) of the third party mitochondrial DNA on normal development is not totally clear at this stage.

The wording of this clause avoids any references to cytoplasmic transfer explicitly and instead utilises wording that reflects the concern that it results in the creation of human embryos with genetic material from more than two people. In this way the prohibition is drafted sufficiently broadly to include other techniques, current or emerging, that may also involve the presence in a human embryo of a third party's DNA.

The maximum penalty that may be applied for creating or developing a human embryo containing genetic material provided by more than 2 persons is 10 years imprisonment.

Clause 16—Offence—developing human embryo outside body of woman for longer than 14 days

This clause requires that a human embryo created outside the body of a woman must not be allowed to develop beyond 14 days. This does not include any time that the embryo's development is suspended whilst in storage (for example while the embryo is frozen).

In practice, this means that human embryos created by ART must be implanted, stored or allowed to succumb (if unsuitable for implantation or excess to the needs of the couple for whom the embryo was created) before the 14th day of their development. It is standard ART clinical practice for embryos to be implanted when they have reached between three and seven days of development.

It is important that this clause be read subject to clause 13 that bans the creation of a human embryo by any means other than the fertilisation of human egg by human sperm. This means that a human embryo created by asexual means, such as by parthenogenesis, embryo splitting or somatic cell nuclear transfer, cannot be created or developed to any stage.

This clause provides that the maximum penalty for developing a human embryo outside the body of a woman for more than 14 days is 10 years imprisonment.

Clause 17—Offence—using precursor cells to create human embryo etc

This clause prevents the creation of a human embryo with cells taken from another human embryo or a human foetus that have the potential to develop into egg or sperm cells. It is also an offence to develop a human embryo created by precursor cells of eggs or sperm taken from an embryo or foetus. The purpose of this clause is to prevent individuals from obtaining precursor cells and using these cells in an attempt to develop a human embryo whether for reproductive or any other purposes. The reasons for this practice being prohibited is that if precursor cells were to be used in such an attempt then children could potentially be born (using ova and/or sperm derived from a foetus or embryo) never having had a living genetic parent.

The maximum penalty for using precursor cells from a human embryo or a human foetus to create a human embryo, or develop such an embryo, is 10 years imprisonment.

Clause 18—Offence—heritable alterations to genome

This clause prohibits any manipulation of a human genome that is intended to be heritable, that is, able to be passed on to subsequent generations of humans. This clause bans what is commonly referred to as germ line gene therapy. In germ line gene therapy, changes would be made to the genome of egg or sperm cells, or even to the cells of the early embryo. The genetic modification would then be passed on to any offspring born to the person whose cell was genetically modified and also to subsequent generations.

The maximum penalty for manipulating the human genome so that the change is heritable to future generations is 10 years imprisonment.

Clause 19—Offence—collecting viable human embryo from woman's body

This clause prevents the removal of viable human embryos from the body of a woman after fertilisation has taken place *in vivo* - a practice sometimes referred to as embryo flushing. Embryo flushing is commonly used in animal husbandry and while there have been no recent reports of it being used in humans there is a concern that a healthy human embryo could be removed from a woman's uterus before it implants so that it could be used for research or for transfer to another woman. This clause bans such a practice.

The maximum penalty for intentionally collecting a viable human embryo from a woman is 10 years imprisonment.

Clause 20—Offence—creating chimeric or hybrid embryo

This clause makes it an offence to intentionally create a chimeric embryo or to intentionally create a hybrid embryo.

It is not intended that this clause prohibit the creation of transgenic animals. Transgenic animals are created through the insertion of one or more foreign genes (including human genes) into an animal embryo. It is important to note that transgenic animals are regulated under the *Gene Technology Act 2000* (Cwth) as a genetically modified organism. Before anyone could genetically modify an animal embryo, a licence must be sought from the Gene Technology Regulator. The Gene Technology Regulator would conduct a comprehensive risk assessment and may seek advice on the ethical issues posed by this practice from the Gene Technology Ethics Committee. Any such work would also need to meet the requirements of an Animal Welfare Committee (in accordance with NHMRC Guidelines).

The maximum penalty for creating, or developing, a hybrid or chimeric embryo is 10 years imprisonment.

Clause 21—Offence—placing of embryo

This clause prevents the placement of:

- a human embryo in an animal;
- a human embryo into the body of a human, including a man or any part of a woman's body, other than the female reproductive tract;
- an animal embryo in a human, for any period of gestation.

Some concern has also been expressed about the possibility, in the future, of a human embryo being developed into a foetus, outside the body of a woman. This would be prevented by clause 16 that prohibits the development of an embryo *in vitro* for any period longer than 14 days.

The maximum penalty for any of the offences under this clause is 10 years imprisonment.

Clause 22—Offence—importing, exporting or placing a prohibited embryo

This clause prevents the intentional import into the ACT, intentional export from the ACT or the intentional placement in the body of a woman of any embryo that is referenced in clauses 13, 14, 15, 16, 17, 18, 19 and 20. For the purposes of this clause, such embryos are referred to as prohibited embryos.

That is:

- a human embryo created by a process other than the fertilisation of a human egg by human sperm;
- a human embryo created outside the body of a woman, unless the intention of the person who created the embryo was to attempt to achieve pregnancy in a particular woman;
- a human embryo that contains genetic material provided by more than 2 persons;
- a human embryo that has been developing outside the body of a woman for a period of more than 14 days, excluding any period throughout which development is suspended;
- a human embryo created using precursor cells taken from a human embryo or a human fêtes;
- a human embryo that contains a human cell whose genome has been altered in such a way that the alteration is heritable by human descendants of the human whose cell was altered;
- a human embryo that was removed from the body of a woman by a person intending to collect a viable human embryo; or
- a chimeric embryo or a hybrid embryo.

By including both importation and implantation within this clause it removes the possibility that one person will be able to import a prohibited embryo and give it to another person to be implanted in a woman. In this case both people would be in breach of the legislation. Including exportation of a prohibited embryo as an offence ensures that a person cannot export a prohibited embryo that has been illegally created or obtained.

The maximum penalty for importing, exporting or placing in the body of a woman, a prohibited embryo is 10 years imprisonment.

Clause 23—Offence—commercial trading in human eggs etc.

This clause prevents the commercial trading of human eggs, sperm and embryos. Both parties that are involved in commercial trading of such material would be committing an offence (for example, the person who sells the egg, sperm or embryo and the person who purchases the egg, sperm or embryo). The only consideration that may be given in relation to the supply of gametes or embryos is reimbursement of reasonable expenses related to that supply, including expenses incurred for the collection, storage and transport where relevant. This means if, for example, semen is transferred from one clinic to another, the second clinic could reimburse the first clinic for the costs of storage and transport of the semen. A further example is where a woman who is to be treated with donated eggs could pay for the cost of the egg retrieval from another woman.

Reasonable expenses in relation to the supply of a human embryo, where that embryo is donated to another couple, do not include any expenses incurred by the person or couple (for whom the embryo was originally created), before

the embryo was determined to be excess to their needs. That is, if a person has embryos that are excess to their needs and they wish to donate the embryos to other people, they cannot have the costs of their IVF treatment reimbursed by the person receiving the donated embryos.

This clause is not intended to address the issue of surrogacy. It is proposed that surrogacy continue to be dealt with through State and Territory legislation and that it not be addressed as part of this particular national scheme.

The maximum penalty for trading in human embryos, sperm or eggs is 10 years imprisonment.

PART 3 MISCELLANEOUS

Clause 24—Review of operation of Act

This clause requires that the Minister review the operation of the Act as soon as practicable 2 years after the Act commences. In considering and reporting on the scope of the Act the review must take in account the following:

- developments in technology in relation to ART;
- developments in medical and scientific research and the potential application of such research;
- community standards; and
- the acceptability of establishing a National Stem Cell Bank.

Clause 25—Regulation-making power

Clause 25 provides the Executive with the power to make necessary regulations for this Bill. The regulations must be presented to the Legislative Assembly.

Dictionary

The dictionary at the end of the Bill defines key words and phrases that are used in the Bill and is part of the Bill. These definitions determine the meaning that is to be attributed to certain words or phrases whenever they are used in the Bill or regulations.